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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,793	09/19/2000	Volker Zimmer	RDID0043US	1444

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EXAMINER	
QUAN, ELIZABETH S	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 06/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/554,793	ZIMMER, VOLKER	
	Examiner	Art Unit	
	Elizabeth Quan	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-5,7 and 9-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5,7 and 9-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02262004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/26/2004 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 2-5, 7, 9-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 9, 16, 17, and 26 are rendered indefinite since it is unclear whether the edge of the "...sample application opening defined by at least one edge..." is the same as the edges of "...cover having a surface and first and second opposite edges..."

5. Claims 3, 20, and 29 are rendered indefinite since it is unclear on what structure the notches are staggered on opposite sides. Furthermore, these claims are directly dependent on respective independent claims, which recite "at least one notch", such that having only one notch satisfies the independent claim while claims 3, 20, and 29 require multiple notches in order for them to be staggered. A plurality of notches or at least two notches must be positively recited before introducing the "staggered" limitation.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 4, 5, 9-14, 16-18, 21, 22, 24-26, 27, 30, 31, 33, 34 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,843,691 to Douglas et al.

Douglas et al. disclose a method for withdrawing a liquid sample into an analytical by providing a device comprising a carrier (26), detection element (1-8,10) with reagent-impregnated assay areas (1-8) on a membrane (10), first cover (24), intermediate absorbent layers (20,22), and second cover (36) (figs. 2 and 3).

The detection element has opposite first and second ends defined by the intersection between the detection element and intermediate absorbent layer (22) and intersection between the detection element and intermediate absorbent layer (20) and vice versa (figs. 2 and 3). Both intermediate layers are between the second cover and the carrier (figs. 2 and 3).

The first cover appears to be in two portions in which the first portion is defined by a plurality of notches in between fingers and the second portion appears to be a generally, flat, rectangular substrate (figs. 2 and 3). In either the first or second cover portion of the first cover the second edge may be considered the portion that encircles and faces the assay areas (1-8) or the portion facing and sitting on the membrane (figs. 2 and 3).

The first cover cooperates with a surface of the carrier and with the detection element to form a capillary active channel (32) since the detection element forms the bottom surface of the channel, the cover forms the sidewalls of the channel, and the carrier forms the top surface of the channel (figs. 2 and 3). The channel has a sample application opening (30) defined by at least one edge (figs. 2 and 3). The channel extends at least from the opening to the second end of the detection element (figs. 2 and 3).

A notch (28) in the form of a partial groove is positioned at the at least one edge of the sample application opening of the channel such that one side of the edge of the sample application opening is at least partially interrupted by the notch and the surface facing the channel opposite to the at least one notch is exposed (figs. 2 and 3). The notch has a width less than that of the channel, e.g. certain portions of the channel in which the assay areas are encircled by notches and bordered by fingers or considering or interpreting the width of the capillary channel as the distance from the points of intersections with the intermediate absorbent layers (figs. 2 and 3).

The entire surface of the channel formed by the detection element, including the surface exposed by the notch, is hydrophilic (col. 10, lines 60 and 61). The hydrophilicity of the channel is obtained by using a hydrophilic material for the detection element, which is in the form of a layer (figs. 2 and 3).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 2-5, 9, 11-14, 16, 17, 19-22, 24-26, 28-31, 33, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0138152 to Lilja.

Lilja discloses a method for withdrawing a liquid sample into an analytical by providing a device comprising a carrier (10), detection element comprising a hydrophilic reagent-impregnated membrane (11), and cover (11)(figs. 5 and 5a). Since the membrane may be formed of several layers, the layer that is not impregnated with reagent may be considered the cover and the layer that is impregnated with reagent or directly forming the capillary channel may be considered the detection element. The detection element has opposite first and second ends, and the cover has a surface and first and second opposite edges (figs. 5 and 5a). The carrier, cover, and detection element are in a sandwich configuration cooperating to form the capillary active channel (26). The current language of the claim "...cover cooperating with a surface of the carrier and with the detection element to form a capillary-active channel..." does not require the cover to be directly contacting the surface of the carrier. According to Merriam-Webster Dictionary, cooperate is defined as **1 :** to act or work with another or others **:** act together **2 :** to associate with another or others for mutual benefit. In the sandwich configuration, the

cover, carrier, and detection element along with their respective surfaces cooperate to form the channel. The surfaces of the cover act, work, and associate with the surfaces of the membrane and the surfaces of the carrier to provide the channel. The channel comprises a sample application opening defined by at least one edge, and the channel extends from the opening to the second end of the detection element (figs. 5 and 5a). At least one notch in the form of a partial grove is positioned at the edge of the sample application opening of the channel (figs. 5 and 5a).

Lilja does not disclose one of the cover or carrier without notches and the other with notches, such that one side of the edge of the sample application opening is at least partially interrupted by the at least one notch and the surface facing the channel opposite to the at least one notch is exposed. However, it would have been obvious to one having ordinary skill in the art provide one of the cover or carrier without notches and the other with notches in the device of Lilja to provide a platform accommodating sample liquid to prevent leakage and spillage and ultimately contamination.

Lilja fails to disclose the at least one notch having a width less than that of the channel. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the at least one notch of Liljz such that the width of the at least one notch is less than that of the channel to provide a smaller amount of solution to be admitted to the channel or drawn in by wicking or capillary action.

Lilja shows a plurality of notches (fig. 5). According to Merriam-Webster Collegiate Dictionary, stagger is defined as to arrange in any of various zigzags, alternations, or overlappings of position or time, and alternations is defined as causing to alternate, which is

defined as arranged first on one side and then on the other at different levels or points along an axial line or arranged one above or alongside the other. It is noted that the notches are arranged one above or alongside the other depending on the frame of reference and inherently arranged first on one side and then on the other at different levels or points along an axial line, as imperfections inherently exist.

11. Alternatively, claims 2-5, 9, 11-14, 16, 17, 19-22, 24-26, 28-31, 33, 34 rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0138152 to Lilja in view of U.S. Patent No. 5,942,102 to Hodges et al.

Lilja fails to disclose the at least one notch having a width less than that of the channel. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the at least one notch of Lilja such that the width of the at least one notch is less than that of the channel to provide a small amount of solution to be admitted to the channel or drawn in by wicking or capillary action and allow air to escape as taught by Hodges et al. (COL. 5, lines 3-6, 11, and 12).

12. Claims 2-5, 9, 11-14, 16, 17, 19-22, 24-26, 28-31, 33, 34 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent N. 5,942,102 to Hodges et al.

Hodges et al. disclose a method for withdrawing a liquid sample into an analytical by providing a device comprising a carrier, detection element, and cover (figs. 9-11). The detection element has opposite first and second ends, and the cover has a surface and first and second opposite edges (figs. 5 and 5a). The carrier, cover, and detection element are in a sandwich configuration cooperating to form the capillary active channel (8). The channel comprises a sample application opening defined by at least one edge, and the channel extends from the

opening to the second end of the detection element (figs. 5 and 5a). At least one notch in the form of a partial grove is positioned at the edge of the sample application opening of the channel (figs. 5 and 5a).

Hodges et al. do not disclose one of the cover or carrier without notches and the other with notches, such that one side of the edge of the sample application opening is at least partially interrupted by the at least one notch and the surface facing the channel opposite to the at least one notch is exposed. However, it would have been obvious to one having ordinary skill in the art provide one of the cover or carrier without notches and the other with notches in the device of Hodges et al. to provide a platform accommodating sample liquid to prevent leakage and spillage and ultimately contamination.

It is unclear how the reagents GOD and ferrocyanide is contained within the cell. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made modify the device of Hodges et al. to provide the reagents GOD and ferrocyanide in the membrane (4), such that the membrane, cover with its coating (2), and carrier with its coating (6) form the channel, or provide reagents GOD and ferrocyanide in the coatings (2,6) since they are very well known methods of providing reagents through insoluble matter. The current language of the claim "...cover cooperating with a surface of the carrier and with the detection element to form a capillary-active channel..." does not require the cover to be directly contacting the surface of the carrier. According to Merriam-Webster Dictionary, cooperate is defined as **1 :** to act or work with another or others **:** act together

2 : to associate with another or others for mutual benefit. In the latter method of providing reagents, the cover, carrier, and detection element along with their respective surfaces cooperate

to form the channel. The surfaces of the cover act, work, and associate with the surfaces of the membrane and the surfaces of the carrier to provide the channel.

Hodges et al. show two notches (fig. 9). According to Merriam-Webster Collegiate Dictionary, stagger is defined as to arrange in any of various zigzags, alternations, or overlappings of position or time, and alternations is defined as causing to alternate, which is defined as arranged first on one side and then on the other at different levels or points along an axial line or arranged one above or alongside the other. It is noted that the notches are arranged one above or alongside the other depending on the frame of reference and inherently arranged first on one side and then on the other at different levels or points along an axial line, as imperfections inherently exist.

13. Claims 2, 3, 19, 20, 28, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,843,691 to Douglas et al. in view of U.S. Patent No. 4,439,526 to Columbus or U.S. Patent No. 5,942,102 to Hodges et al. or EP 0138152 to Lilja.

Referring to claims 2, 19, 28, Douglas et al. do not disclose at least two notches next to each other. However, in the field of capillary fluid flow, it is known to provide a plurality of access means to the capillary to facilitate fluid flow into the capillary channel. See, for example, Columbus, abstract; column 2, lines 29-46 and column 6, lines 63 through column 7, line 2. It would have been obvious to one or ordinary skill in the art to provide at least 2 notches (access means) at the entrance of the channel in the device of Douglas et al. or Hodges et al. or Lilja in order to facilitate fluid flow in the channel.

Referring to claims 3, 20, 29, according to Merriam-Webster Collegiate Dictionary, stagger is defined as to arrange in any of various zigzags, alternations, or overlappings of

position or time, and alternations is defined as causing to alternate, which is defined as arranged first on one side and then on the other at different levels or points along an axial line or arranged one above or alongside the other. It is noted that the two notches of Douglas et al. or Hodges et al. or Lilja are arranged one above or alongside the other depending on the frame of reference and inherently arranged first on one side and then on the other at different levels or points along an axial line, as imperfections inherently exist.

14. Claims 7, 15, 23, 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,843,691 to Douglas et al. or EP 0138152 to Lilja alternatively in view of U.S. Patent No. 5,942,102 to Hodges et al. or U.S. Patent No. 5,942,102 to Hodges et al. in view of U.S. Patent No. 6,238,624 to Heller et al.

Referring to claims 7, 15, 23, 32, Douglas et al. and Lilja alternatively in view of Hodges et al. and Hodges et al. do not disclose using oxidized aluminum for hydrophilization. Heller et al. disclose forming lawn type permeation layers by attaching bifunctional linear or polymeric hydrophilic molecules to a metal surface in fabricating a microelectronic device to carry out and control multi-step and multiplex molecular biological reactions in microscopic format, which are significant in clinical diagnostics (see ABSTRACT; COL. 16, lines 55-64). The preferred procedure for producing a lawn type structure involves derivatization of the metal microelectrode surface using aminopropyltriethoxy silane (APS) (see COL. 17, lines 13-15). APS provides a combined permeation and attachment layer with primary amine groups for covalent coupling of binding entities, especially oligonucleotides (see COL. 17, lines 17-19, 38, and 39). APS provides a high level of functionalization in terms of surface binding sites on slightly oxidized aluminum (see COL. 17, lines 20-22). Therefore, it would have been obvious to one having

ordinary skill in the art at the time the invention was made to use oxidized aluminum for hydrophilization as in Heller et al. in the device of Douglas et al. or Lilja alternatively in view Hodges et al. or Hodges et al. to provide a high level of surface binding sites to bind targeted entities in sample liquid diagnostics.

Response to Arguments

15. Applicant's arguments with respect to claims 2-5, 7, and 9-34 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (571) 272-1261. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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